



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Agency Information Collection Activities: Proposed Collection: Public Comment Request

#### Information Collection Request Title: Data System for Organ Procurement and

#### Transplantation Network, OMB No. 0915-0157 – Revision

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement for the opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

**DATES:** Comments on this ICR should be received no later than **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

**ADDRESSES:** Submit your comments to [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443-1984.

**SUPPLEMENTARY INFORMATION:** When submitting comments or requesting information, please include the information request collection title for reference.

*Information Collection Request Title:* Data System for Organ Procurement and Transplantation Network, OMB No. 0915- 0157 – Revision

*Abstract:* Section 372 of the Public Health Service Act requires that the Secretary, by contract, provide for the establishment and operation of a private, non-profit entity: the Organ Procurement and Transplantation Network (OPTN). The data collected pursuant to the OPTN's regulatory authority in 42 CFR 121.11 of the OPTN Final Rule is collected through OMB approved data collection forms. Therefore, data approved for collection by the OPTN Board of Directors are submitted by HRSA for OMB approval under the Paperwork Reduction Act of 1995.

This is a request for revising the current OPTN data collection associated with an individual's clinical characteristics at the time of registration, transplant, and follow-up after the transplant to include data collection forms in the OPTN Organ Labeling, Packaging, and Tracking System, the OPTN Kidney Paired Donation Pilot Program (KPDPP), and the OPTN Patient Safety Reporting Portal (PSRP). This revision also includes OPTN Board of Directors approved changes to the existing OMB data collection forms. These specific data elements of the OPTN data system are collected from transplant hospitals, organ procurement organizations, and histocompatibility laboratories. The information is used to (1) facilitate organ placement and match donor organs with recipients; (2) monitor compliance of member organizations with Federal laws and regulations and with OPTN requirements; (3) review and report periodically to the public on the status of organ donation and transplantation in the United States; (4) provide data to researchers and government agencies to study the scientific and clinical status of organ transplantation; (5) perform transplantation-related public health surveillance including the possible transmission of donor disease.

HRSA is submitting the following changes to improve the OPTN organ matching and allocation process and improve OPTN member compliance with OPTN requirements. All of these proposed changes have been approved by the OPTN Board of Directors.

- 1) Adding two data collection forms for the OPTN Organ Labeling, Packaging, and Tracking System to the existing OMB approved Data System for Organ Procurement and

Transplantation Network. The system has two forms that are used through mobile and web-based applications to ensure the correct organ is transplanted into the correct patient, minimize labeling and transport errors, accelerate organ information transfer, and capture data regarding organ procurement. OPTN Organ Labeling, Packaging, and Tracking System is comprised of two data collection forms: organ labeling and packaging, and organ tracking and validating.

- 2) Adding data collection forms for the OPTN KPDPP to the existing OMB approved Data System for Organ Procurement and Transplantation Network. Kidney paired donation is a transplant option for those patients waiting for a kidney transplant who have a willing living donor who is medically able but cannot donate a kidney to their intended candidate because they are incompatible. OPTN KPDPP matches living donors, and their intended candidates with other living donors or intended candidate pairs when the living donors cannot donate to the person(s) they initially hoped would receive their kidney. OPTN KPDPP is comprised of three data collection forms: candidate registration, donor registration, and match offer management.
- 3) Adding data collection forms in the OPTN PSRP to the existing OMB approved Data System for Organ Procurement and Transplantation Network. OPTN PSRP allows the OPTN to collect reports on any event or process variance that could cause concerns from transplantation, donation, safety, or quality perspective. OPTN PSRP is comprised of four data collection forms: disease transmission event, living donor event, safety situation, and potential disease transmission.
- 4) Additional revisions to existing data collection forms were made based on the OPTN Board of Directors-approved changes to improve organ matching, allocation, and OPTN policy compliance.

*Need and Proposed Use of the Information:* Data are used to develop transplant, donation, and allocation policies, to determine whether institutional members are complying with

policy, to determine member-specific performance, to ensure patient safety, and to fulfill the requirements of the OPTN Final Rule. The practical utility of the data collection is further enhanced by requirements that the OPTN data must be made available, consistent with applicable laws, for use by OPTN members, the Scientific Registry of Transplant Recipients, the Department of Health and Human Services, and members of the public for evaluation, research, patient information, and other important purposes.

*Likely Respondents:* Transplant programs, Organ Procurement Organizations, and Histocompatibility Laboratories.

*Burden Statement:* Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems to collect, validate, and verify information, process and maintain information, and disclose and provide information; to train personnel and be able to respond to a collection of information; to search data sources; to complete and review the collection of information, and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

Total Estimated Annualized Burden Hours:

Form Name	Number of Respondents	Number of Responses per Respondent *	Total Responses	Average Burden per Response (in hours)	Total Burden Hours
Deceased Donor Registration	57	188.26	10,731	1.10	11,804
Living Donor Registration	300	22.85	6,855	2.19	15,012 <sup>a</sup>
Living Donor Follow-up	300	62.23	18,669	1.53	28,564 <sup>b</sup>
Donor Histocompatibility	147	123.99	18,227	0.20	3,645
Recipient Histocompatibility	147	225.10	33,090	0.40	13,236
Heart Transplant Candidate Registration	140	33.69	4,717	0.90	4,245

Heart Recipient Registration	140	24.33	3,406	1.20	4,087
Heart Follow Up (6 Month)	140	22.01	3,081	0.40	1,233
Heart Transplant Recipient Follow Up 1-5 Year	140	90.61	12,685	0.90	11,417
Heart Transplant Recipient Follow Up Post 5 Year	140	153.97	21,556	0.50	10,778
Heart Post-Transplant Malignancy Form	140	12.77	1,788	0.90	1,609
Lung Transplant Candidate Registration	71	45.21	3,210	0.90	2,889
Lung Transplant Recipient Registration	71	35.66	2,532	1.20	3,038
Lung Transplant Recipient Follow Up 6 Month	71	32.35	2,297	0.50	1,148
Lung Transplant Recipient Follow Up 1-5 Year	71	118.85	8,438	1.10	9,282
Lung Transplant Recipient Follow Up Post 5 Year	71	116.49	8,271	0.60	4,962
Lung- Post-Transplant Malignancy Form	71	19.72	1,400	0.40	560
Heart/Lung Transplant Candidate Registration	69	0.97	67	1.10	74
Heart/Lung Recipient Registration	69	0.46	32	1.30	41
Heart/Lung Transplant Recipient Follow Up 6 Month	69	0.45	31	0.80	25
Heart/Lung Transplant Recipient Follow Up 1-5 Year	69	1.14	79	1.10	87
Heart/Lung Transplant Recipient Follow Up Post 5 Year	69	3.30	228	0.60	137
Heart/Lung Post-Transplant Malignancy Form	69	0.30	21	0.40	8
Liver Transplant Candidate Registration	146	90.29	13,182	0.80	10,546
Liver Transplant Recipient Registration	146	56.55	8,256	1.20	9,908
Liver Transplant Recipient Follow-Up 6 Month - 5 Year	146	266.57	38,919	1.00	38,919
Liver Transplant Recipient Follow-up Post 5 Year	146	316.61	46,225	0.50	23,113
Liver Recipient Explant Pathology Form	146	10.58	1,545	0.60	927
Liver Post-Transplant Malignancy	146	16.35	2,387	0.80	1,910
Intestine Transplant Candidate Registration	20	6.95	139	1.30	181
Intestine Transplant Recipient Registration	20	5.20	104	1.80	187
Intestine Transplant Recipient Follow Up 6 Month - 5 Year	20	26.20	524	1.50	786

Intestine Transplant Recipient Follow Up Post 5 Year	20	37.20	744	0.40	298
Intestine Post-Transplant Malignancy Form	20	2.10	42	1.00	42
Kidney Transplant Candidate Registration	237	168.77	39,998	0.80	31,999
Kidney Transplant Recipient Registration	237	89.43	21,195	1.20	25,434
Kidney Transplant Recipient Follow-Up 6 Month - 5 Year	237	431.86	102,351	0.90	92,116
Kidney Transplant Recipient Follow-Up Post 5 Year	237	449.40	106,508	0.50	53,254
Kidney Post-Transplant Malignancy Form	237	22.64	5,366	0.80	4,293
Pancreas Transplant Candidate Registration	133	2.77	368	0.60	221
Pancreas Transplant Recipient Registration	133	1.46	194	1.20	233
Pancreas Transplant Recipient Follow-Up 6 Month - 5 Year	133	7.87	1,047	0.50	523
Pancreas Transplant Recipient Follow-Up Post 5 Year	133	15.93	2,119	0.50	1,059
Pancreas Post-Transplant Malignancy Form	133	0.73	97	0.60	58
Kidney/Pancreas Transplant Candidate Registration	133	9.75	1,297	0.60	778
Kidney/Pancreas Transplant Recipient Registration	133	7.73	1,028	1.20	1,234
Kidney/Pancreas Transplant Recipient Follow-Up 6 Month - 5 Year	133	32.80	4,362	0.50	2,181
Kidney/Pancreas Transplant Recipient Follow-Up Post 5 Year	133	57.80	7,687	0.60	4,612
Kidney/Pancreas Post-Transplant Malignancy Form	133	2.20	293	0.40	117
VCA Transplant Candidate Registration	27	0.89	24	0.40	11
VCA Transplant Recipient Registration	27	1.59	43	1.36	58 <sup>c</sup>
VCA Transplant Recipient Follow Up	27	0.67	18	1.31	24 <sup>d</sup>
Organ Labeling and Packaging	57	208.25	11,870	0.18	2,137
Organ Tracking and Validating	34	169.06	5,748	0.08	460
Kidney Paired Donation Candidate Registration	160	1.38	221	0.29	64
Kidney Paired Donation Donor Registration	160	1.46	234	1.07	250

Kidney Paired Donation Match Offer Management	160	1.51	242	0.67	162
Disease Transmission Event	308	1.44	444	0.62	275
Living Donor Event	251	0.12	30	0.56	17
Safety Situation	450	0.48	216	0.56	121
Potential Disease Transmission	57	6.88	392	1.27	498
Request to Unlock	450	39.22	17,649	0.02	353
<b>Total</b>	<b>8,290</b>		<b>604,519</b>		<b>437,240</b>

\*The Number of Responses per Respondent was calculated by dividing the Total Responses by the Number of Respondents and rounding to the nearest tenth.

- a) Total burden increased due to the approval of the “Modify Data Collection on VCA Living Donors” proposal approved by the OPTN Board of Directors (BOD) in December of 2020. The proposal required adding 54 new data fields onto this form and removing 1 data field from this form.
- b) Total burden increased due to the approval of the “Modify Data Collection on VCA Living Donors” proposal approved by the OPTN BOD in December of 2020. The proposal required adding 17 new data fields onto this form.
- c) Total burden increased due to the approval of the “Programming VCA Allocation in UNet” proposal approved by the OPTN BOD in December of 2020. The proposal required adding 16 new data fields onto this form and removing 10 data fields from this form.
- d) Total burden increased due to the approval of the “Programming VCA Allocation in UNet” proposal approved by the OPTN BOD in December of 2020. The proposal required adding 54 new data fields onto this form and removing 5 data fields from this form.

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency’s functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**Maria G. Button,**

*Director, Executive Secretariat.*

[FR Doc. 2021-18688 Filed: 8/30/2021 8:45 am; Publication Date: 8/31/2021]